

Appl. No. 10/600,290
Amdt. dated July 6, 2006
Reply to Office action of April 17, 2006

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REMARKS

Priority

Priority to Application No. 09/391,260 has been denied for failing to provide adequate support for decreasing expression of a gene using double strand RNA. Applicants respectfully disagree. '260 teaches on page 5 lines 11-16, "The term includes deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) in the form of an oligonucleotide messenger RNA, anti-sense, plasmid DNA, parts of a plasmid DNA or genetic material derived from a virus. A polynucleotide is distinguished, here, from a oligonucleotide by containing more than 120 monomeric units. Anti-sense is a polynucleotide that interferes with the function of DNA and/or RNA." '260 further teaches on page 6 lines 13-15, "Entry into the cell is required for the polynucleotide to produce the therapeutic protein, to block the production of a protein, or to decrease the amount of a RNA." (*emphasis added*). It is well known in the art that polynucleotides may be double or single stranded.

The Action further states that there is no support in the priority documents of the instant application for decreasing "expression of a gene", particularly using a double stranded RNA. Applicants respectfully disagree. The instant application teaches, on page 1 lines 27-28, "Polynucleotides may be coded to express a whole or partial protein, or may be anti-sense." The instant application defines an antisense polynucleotide, on page 8 lines 33-34, as, "... a polynucleotide that interferes with the function of DNA and/or RNA." The instant application further states, on page 9 lines 12-15, "A polynucleotide can be delivered to a cell to express an exogenous nucleotide sequence, to inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or to express a specific physiological characteristic not naturally associated with the cell. Polynucleotides may be coded to express a whole or partial protein, or may be anti-sense."

Objections to the Claims

Claims 13, 15, 16, and 23-31 are objected to because the elected invention is drawn to a process for delivering a dsRNA that is not expressed, but the claims as pending are broader. Applicants have made the appropriate corrections.

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Objections to the Specification

The specification has been objected to for failing to provide proper antecedent basis for the claimed subject matter. Applicants have amended claims 19 and 20 to reflect the ranges specified in the application on page 8 lines 29-30. Support for inhibiting gene expression is provided in the specification on page 8 lines 33-34 and page 9 lines 12-15.

Rejection of the Claims under 35 USC § 112

Claims 13, 15, 16, 18-20, and 23-31 have been rejected under 35 U.S.C. 112, first paragraph, for failing to support reducing "expression of a gene" with double strand RNA. Applicants respectfully disagree for the reasons stated above and request reconsideration of the rejection.

Double Patenting:

Claims 13, 15, 16, 18-20, and 23-31 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,627,616. With this Response, Applicants have filed a terminal disclaimer to overcome the rejection.

The Examiner's objections and rejections are now believed to be overcome by this response to the Office Action. In view of Applicants' amendment and arguments, it is submitted that claims 13, 19-20, and 23-31 should be allowable.

Respectfully submitted,



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I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as express mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this date: July 7, 2006


Kirk Ekena